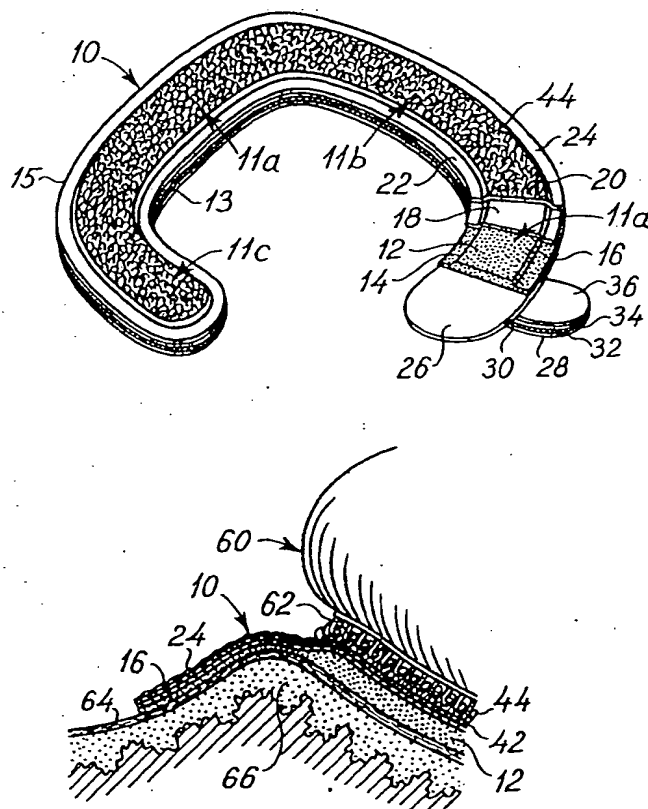


INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁵: A61F 2/52	A1	(11) International Publication Number: WO 94/16650 (43) International Publication Date: 4 August 1994 (04.08.94)
(21) International Application Number: PCT/DK94/00047 (22) International Filing Date: 27 January 1994 (27.01.94) (30) Priority Data: 94/93 27 January 1993 (27.01.93) DK (71) Applicant (for all designated States except US): EUROMED I/S [DK/DK]; Lille Kongevej, DK-3480 Fredensborg (DK). (72) Inventor; and (75) Inventor/Applicant (for US only): JENSEN, Ole [DK/US]; 646 Orangeburgh Road, River Vale, NJ 07675 (US). (74) Agent: TH. OSTENFELD PATENTBUREAU A/S; Bredgade 41, Postboks 1183, DK-1011 Copenhagen K (DK).		(81) Designated States: US, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published With international search report.

(54) Title: FIXATING OF A BREAST PROSTHESIS OR MAMMARY PROSTHESIS TO A THORACIC SURFACE**(57) Abstract**

An adhesive strip assembly (10) for fixing a breast prosthesis (60) to a thoracic skin surface (64) comprises an adhesive strip (12) of a substantially curved configuration corresponding to a part of a circumferential surface of contact of the breast prosthesis at the thoracic skin surface. The adhesive strip defines an outer rim and opposite first and second surfaces. The first surface is provided with an adhesive layer and is adapted to be arranged in contact with the thoracic skin surface for adhering thereto. The adhesive strip assembly further comprises fixation means (20) for releasably fixating the breast prosthesis to the adhesive strip so as to fixate the breast prosthesis to the thoracic skin surface. The fixation means are arranged at the second surface of the adhesive strip (12) covering a part of the second surface thereof and providing an uncovered circumferential surface segment (22, 24) of the second surface adjacent to the outer rim of the adhesive strip. The adhesive strip assembly constitutes a component of a breast prosthesis assembly also comprising the breast prosthesis (60).



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	GB	United Kingdom	MR	Mauritania
AU	Australia	GE	Georgia	MW	Malawi
BB	Barbados	GN	Guinea	NE	Niger
BE	Belgium	GR	Greece	NL	Netherlands
BF	Burkina Faso	HU	Hungary	NO	Norway
BG	Bulgaria	IE	Ireland	NZ	New Zealand
BJ	Benin	IT	Italy	PL	Poland
BR	Brazil	JP	Japan	PT	Portugal
BY	Belarus	KE	Kenya	RO	Romania
CA	Canada	KG	Kyrgyzstan	RU	Russian Federation
CF	Central African Republic	KP	Democratic People's Republic of Korea	SD	Sudan
CG	Congo	KR	Republic of Korea	SE	Sweden
CH	Switzerland	KZ	Kazakhstan	SI	Slovenia
CI	Côte d'Ivoire	LI	Liechtenstein	SK	Slovakia
CM	Cameroon	LK	Sri Lanka	SN	Senegal
CN	China	LU	Luxembourg	TD	Chad
CS	Czechoslovakia	LV	Latvia	TG	Togo
CZ	Czech Republic	MC	Monaco	TJ	Tajikistan
DE	Germany	MD	Republic of Moldova	TT	Trinidad and Tobago
DK	Denmark	MG	Madagascar	UA	Ukraine
ES	Spain	ML	Mali	US	United States of America
FI	Finland	MN	Mongolia	UZ	Uzbekistan
FR	France			VN	Viet Nam
GA	Gabon				

FIXATING OF A BREAST PROSTHESIS OR MAMMARY PROSTHESIS TO A THORACIC SURFACE.

The present invention relates to novel techniques of fixating a breast prosthesis or mammary prosthesis to a thoracic surface.

The technique of fixating a breast or mammary prosthesis body made from e.g. a PU foil in which a silicone filling is enclosed by means of an adhesive strip or adhesive patch which is adhered to the thoracic surface by means of bur fixation, such as velcro or similar fixation means, is well-known within the art.

The provision of a breast prosthesis assembly comprising a separate adhesive strip or adhesive patch and a breast prosthesis body which is fixated to the adhesive strip or adhesive patch by means of releasable fixation means, such as a bur or velcro fixation, is highly advantageous as the adhesive strip or the adhesive patch may be kept in place for a prolonged period of time, such as several days, e.g. a week, allowing that the breast prosthesis body is removed when the user is e.g. sleeping, resting, bathing or showering, still keeping the adhesive strip or adhesive patch adhered to the thoracic surface. Thus, it should be born in mind that a major skin irritation and discomfort situation occurs as the adhesive strip or the adhesive patch is removed. The provision of releasable fixation of the breast or mammary prosthesis body to the adhesive strip or adhesive patch to a great extent reduces the discomfort of the user as the skin irritation is reduced as compared to the use of breast or mammary prostheses which are adhered directly to the thoracic surface of the user.

Still, the fixation of the thoracic body through the adhesive strip or the adhesive patch may in some instances cause certain troubles and discomfort to the user as the releasable fixation may in some instances fail as the weight of the breast prosthesis body may in some instances peel off the adhesive strip or the adhesive patch causing an overall removal of the adhesive strip or the adhesive patch and consequently an overall removal of the breast or mammary prosthesis assembly comprising the breast or mammary prosthesis body and the adhesive strip or the adhesive patch from the thoracic surface of the user. Although the unintentional peeling off of the adhesive strip or adhesive patch from the thoracic surface is to some extent pronounced in case the adhesive strip or adhesive patch is not properly adhered to the thoracic surface

of the user and further in case the breast or mammary prosthesis body is not exactly properly fixated to the adhesive strip or adhesive patch through the releasable fixation, the prior art breast or mammary prosthesis assemblies of the above described type are suffering from a permanent risk that the adhesive strip or the adhesive patch to which the breast or mammary prosthesis body is fixated may be peeled off through the weight of the breast or mammary prosthesis body.

An object of the present invention is to provide an adhesive strip assembly and an adhesive patch assembly for the fixation of a breast or mammary prosthesis body to a thoracic surface of a user which adhesive strip assembly or which adhesive patch assembly reduces, or to any substantial extent eliminates the risk that the adhesive strip assembly or the adhesive patch assembly is peeled off from the adhesion to the thoracic surface by the weight of the breast or mammary prosthesis body.

A further object of the present invention is to reduce, or to any substantial extent eliminate the risk that perspiration at the surface of contact between the breast or mammary prosthesis body and the thoracic surface to which the breast or mammary prosthesis body is fixated may jeopardize the adhesion of the adhesive fixation of the breast or mammary prosthesis body.

A particular feature of the present invention relates to the fact that the force generated by the weight of the breast or mammary prosthesis body which in the prior art adhesive strip or adhesive patch assembly may result in a peeling off of the adhesive strip or adhesive patch assembly is transferred from a peeling off generating force perpendicular to the thoracic surface to which the adhesive strip or adhesive patch assembly is adhered, into a shear force parallel to the surface of adhesion of the adhesive strip or adhesive patch assembly to the thoracic surface of the user.

A particular advantage of the present invention relates to elimination of discomfort of the user originating from perspiration at the thoracic surface of the user to which thoracic surface the breast or mammary prosthesis body is adhered.

According to a first aspect of the present invention, an adhesive strip assembly for fixating a breast prosthesis to a thoracic skin surface is provided, comprising:

an adhesive strip of a substantially curved configuration corresponding to a part of a circumferential surface of contact of said

breast prosthesis at said thoracic skin surface, said adhesive strip defining an outer rim and opposite first and second surfaces, said first surface being provided with an adhesive layer and being adapted to be arranged in contact with said thoracic skin surface for adhering thereto, and

5 fixation means for releasably fixating said breast prosthesis to said adhesive strip so as to fixate said breast prosthesis to said thoracic skin surface, said fixation means being arranged at said second surface of said adhesive strip covering a part of said second surface thereof and providing an uncovered circumferential surface segment of

10 said second surface adjacent to said outer rim of said adhesive strip.

According to a second aspect of the present invention, an adhesive patch assembly for fixating a breast prosthesis to a thoracic skin surface is provided, comprising:

15 an adhesive patch of a configuration corresponding to a part of a surface of contact of said breast prosthesis at said thoracic skin surface, said adhesive patch defining an outer rim and opposite first and second surfaces, said first surface being provided with an adhesive layer and being adapted to be arranged in contact with said thoracic skin

20 surface for adhering thereto, and

fixation means for releasably fixating said breast prosthesis to said adhesive patch so as to fixate said breast prosthesis to said thoracic skin surface, said fixation means being arranged at said second surface of said adhesive patch covering a part of said second surface thereof and providing an uncovered circumferential surface segment of

25 said second surface adjacent to said outer rim of said adhesive patch.

By the provision of an uncovered circumferential surface segment of the second surface of the adhesive strip or adhesive patch adjacent to the outer rim of the adhesive strip or adhesive patch, a circumferential

30 surface segment is provided which is adhered to the thoracic skin surface.

The circumferential surface segment of the adhesive strip or the adhesive patch causes a transfer of the force generated by the weight of the breast or mammary prosthesis body from a force orientated perpendicularly to the thoracic surface to which the adhesive strip or the adhesive patch is adhered, which force might cause a peeling off of the adhesive strip or the adhesive patch along the outer rim of the adhesive strip or the adhesive patch, into a shear force which is orientated pa-

35

parallel to the thoracic surface to which the adhesive patch or the adhesive strip is adhered, which shear force is further transferred to the overall area of adhesion of the circumferential surface segment instead of to a peeling off along the outer rim of the adhesive strip or the
5 adhesive patch.

In accordance with a first embodiment of the adhesive strip assembly and the adhesive patch assembly according to the first and the second aspect, respectively, of the present invention, the fixation means are fixated to the adhesive strip or the adhesive patch at the second surface thereof through an adhesive foil, as the fixation means are not
10 readily fixatable to the adhesive strip. Thus, in case the adhesive strip or the adhesive patch is made from e.g. a hydrocolloid material, and the fixation means are constituted by an adhesive foil or a bur fixation means, a direct contact between the adhesive strip or the adhesive
15 patch made from the hydrocolloid material and the fixation means may not provide a strong and lasting bond and fixation. Through an intermediate adhesive foil which is fixated to the adhesive strip or the adhesive patch and which fixates the fixation means to an adhesive layer of the adhesive foil, a strong and lasting bond between the fixation means and
20 the adhesive strip or the adhesive patch is obtained. The adhesive foil may in some instances be constituted by an adhesive layer, or alternatively be constituted by an adhesive foil comprising a support foil provided with an adhesive layer on one or both side surfaces.

In order to protect the adhesive strip or the adhesive patch from
25 being ruined or contaminated prior to use, the adhesive strip assembly or the adhesive patch assembly is preferably provided with a release paper sheet covering the first surface of the adhesive strip or the adhesive patch prior to the use of the assembly in question.

The fixation means of the adhesive strip assembly and the adhesive
30 patch assembly according to the first and the second aspect, respectively, of the present invention, may be constituted by an adhesive layer which is providing a sufficiently strong bonding to the breast prosthesis for fixating the breast prosthesis to the adhesive layer provided at the second surface of the adhesive strip or the adhesive patch.

35 According to the presently preferred embodiments of the adhesive strip assembly and the adhesive patch assembly according to the present invention, the fixation means are constituted by bur fixation means adapted to cooperate with mating bur fixation means of the breast.

prosthesis. The bur fixation means of the adhesive strip assembly and the adhesive patch assembly may be provided by a bur tape applied to the second side of the adhesive strip and the adhesive patch of the adhesive strip assembly and the adhesive patch assembly, respectively. The bur
5 fixation means of the adhesive strip assembly and the adhesive patch assembly according to the first and the second aspect, respectively, of the present invention may comprise bur loops or alternatively comprise bur hooks.

The uncovered surface segment of the second surface of the adhesive
10 strip and the adhesive patch of the adhesive strip assembly and the adhesive patch assembly, respectively, characteristic of the present invention, may be constituted by a surface segment of the bur tape not being provided with bur fixation means, which surface segment constitutes the force transfer surface segment for transferring a force orientated
15 perpendicularly to the thoracic skin surface to which the adhesive strip assembly or the adhesive patch assembly is adhered, into a shear force parallel to the thoracic skin surface.

The adhesive strip or the adhesive patch of the adhesive strip assembly and the adhesive patch assembly, respectively, may be constituted
20 by any minimum-skin-irritating adhesive material, such as a hydrocolloid material. Examples of hydrocolloid materials are described in EP patent application No. 0 017 401, GB patent application No. 7909967 and further in US patents No. 3,339,546, 4,253,460, 4,258,715, 4,306,551, and 4,307,717. Reference is made to the above patent applications and pa-
25 tents and the above-mentioned US patents are further incorporated in the present specification by reference.

The hydrocolloid adhesive layer may constitute the adhesive strip or the adhesive patch of the adhesive strip assembly or the adhesive patch assembly, respectively, or constitute a layer supported by a sup-
30 port foil, such as a foil made from a plastic material. The fixation means which are preferably constituted by bur fixation means may be fixed directly to the hydrocolloid adhesive layer or through an adhesive foil, such as a glue layer, or to a support foil supporting the hydrocolloid layer.

35 According to a third aspect of the present invention, a breast prosthesis assembly is provided, comprising:

a breast prosthesis body of a configuration similar to a woman's natural breast and defining a surface of contact to be arranged adjacent

to said thoracic skin surface,

said adhesive strip assembly comprising:

an adhesive strip of a substantially curved configuration corresponding to a part of a circumferential part of said surface of contact
5 of said breast prosthesis body, said adhesive strip defining an outer rim and opposite first and second surfaces, said first surface being provided with an adhesive layer and being adapted to be arranged in contact with said thoracic skin surface for adhering thereto, and

fixation means for releasably fixating said breast prosthesis to
10 said adhesive strip so as to fixate said breast prosthesis to said thoracic skin surface, said fixation means being arranged at said second surface of said adhesive strip covering a part of said second surface thereof and providing an uncovered circumferential surface segment of said second surface adjacent to said outer rim of said adhesive strip.

15 According to a fourth aspect of the present invention, a breast prosthesis assembly is provided, comprising:

a breast prosthesis body of a configuration similar to a woman's natural breast and defining a surface of contact to be arranged adjacent to said thoracic skin surface,

20 said adhesive patch assembly comprising:

an adhesive patch of a configuration corresponding to a part of said surface of contact of said breast prosthesis body, said adhesive patch defining an outer rim and opposite first and second surfaces, said first surface being provided with an adhesive layer and being adapted to
25 be arranged in contact with said thoracic skin surface for adhering thereto, and

fixation means for releasably fixating said breast prosthesis to said adhesive patch so as to fixate said breast prosthesis to said thoracic skin surface, said fixation means being arranged at said second
30 surface of said adhesive patch covering a part of said second surface thereof and providing an uncovered surface segment of said second surface adjacent to said outer rim of said adhesive patch.

The breast prosthesis assemblies according to the third and fourth aspects of the present invention may comprise any of the characteristics
35 of the adhesive strip assembly and the adhesive patch assembly according to the first and the second aspect, respectively, of the present invention.

According to a fifth aspect of the present invention, a breast

prosthesis is provided, comprising:

a breast prosthesis body of a configuration similar to a woman's natural breast and defining a surface of contact to be arranged adjacent to said thoracic skin surface, and a bur fixation means provided at said surface of said breast prosthesis body for fixating a perspiration pad
5 to said surface.

The breast prosthesis according to the fifth aspect of the present invention is particularly advantageous as to the elimination of discomfort of the user originating from perspiration at the thoracic surface
10 of the user, to which thoracic surface the breast or mammary prosthesis body is adhered. By the provision of a perspiration pad which is fixated to the surface of contact of the breast prosthesis body according to the fifth aspect of the present invention, the risk that the adhesion of the breast prosthesis body to the thoracic skin surface, preferably through
15 an adhesive strip assembly or an adhesive patch assembly according to the first and the second aspect, respectively, of the present invention, is reduced or ruined through excessive perspiration at the thoracic skin surface to which the breast prosthesis is adhered. The breast prosthesis assembly according to the fifth aspect of the present invention is preferably constituted by a breast prosthesis body comprising an outer PU
20 foil enclosing a silicone filling thereof.

The present invention will now be further described with reference to the drawings, in which

Fig. 1 is a perspective, partly sectional and schematic view of an
25 adhesive strip assembly of a breast or mammary prosthesis,

Figs. 2 and 3 are schematic and sectional views illustrating a technique of preparing a rim part of the adhesive strip assembly shown in Fig. 1,

Fig. 4 is a schematic and sectional view of the application of the
30 adhesive strip assembly shown in Fig. 1 for fixating a breast prosthesis illustrating a particular feature regarding the fixation of the breast prosthesis,

Fig. 5 is a schematic and sectional view similar to the view of Fig. 4 illustrating a prior art adhesive strip assembly and a disadvantage of the prior art adhesive strip assembly,
35

Fig. 6 is a perspective, partly sectional and schematic view similar to the view of Fig. 1 of an adhesive patch assembly of a breast or mammary prosthesis, and

Fig. 7 is a perspective view of a breast prosthesis to be used in connection with the adhesive strip assembly shown in Figs. 1 and 4, and further comprising a means for receiving and detachably fixating a perspiration absorbing pad.

5 In Fig. 1, an adhesive strip assembly designated the reference numeral 10 in its entirety is shown. The adhesive strip assembly 10 is of a configuration generally comprising two larger adhesive strip segments 11a and 11b which are integrally connected to one another at first ends thereof in a substantially orthogonal structure and further two minor
10 adhesive strip segments 11c and 11d which are integrally connected to a respective larger adhesive strip segment 11a and 11b, respectively, at second ends thereof in substantially orthogonal structures. The adhesive strip assembly 10 is of an overall configuration corresponding to a larger part, such as a 270° segment of a circumferential surface of contact
15 of a breast prosthesis.

The adhesive strip assembly 10 centrally comprises a hydrocolloid adhesive body 12 provided with shallow rim segments 14 and 16 extending along inner and outer rims 13 and 15, respectively, of the adhesive strip assembly 10 and enclosing a central, thicker part of the hydro-
20 colloid adhesive body 12. On top of the hydrocolloid adhesive body 12 and the rim segments 14 and 16 thereof, an adhesive foil 18 is arranged, which adhesive foil is provided with an adhesive layer for the fixation of a bur tape 20. The bur tape 20 is of the type comprising bur loops or hooks for cooperating with a corresponding bur tape of a breast or mam-
25 mary prosthesis comprising bur hooks or loops, respectively. The bur tape 20 shown in Fig. 1 comprises a plurality of bur loops at the central area of the bur tape 20 as the bur tape 20 is not provided with bur loops at the rim segments of the bur tape 20 corresponding to the rim segments 14 and 16 of the hydrocolloid adhesive body 12.

30 The hydrocolloid body 12 is opposite to the adhesive foil 18 provided with a siliconized release paper 26 serving the purpose of protecting the hydrocolloid adhesive body prior to use of the adhesive strip assembly 10. From the siliconized release paper 26, a flap 28 extends outwardly from the adhesive strip assembly 10, which flap 28
35 serves the purpose of making the process of removing the siliconized release paper 26 from the adhesive strip assembly easier. On top of the flap 28 of the siliconized release paper 26, a hydrocolloid adhesive layer 32, an adhesive foil layer 34 and a bur tape layer 36 are ar-

5 ranged. The hydrocolloid adhesive layer, the adhesive foil layer 32, and the bur tape layer 34 originate from the hydrocolloid adhesive body 12, the adhesive foil 18 and the bur tape 20, respectively, and are separated therefrom by a cut 30 which is produced at the stage of cutting the adhesive strip assembly 10 from a sandwich of layers from which the adhesive strip assembly 10 is produced. Thus, the adhesive strip assembly 10 is produced from a sandwich of layers comprising a siliconized release paper layer from which the siliconized release paper 26 comprising the flap 28 is produced, a hydrocolloid adhesive layer from which the hydrocolloid adhesive body 12 and the hydrocolloid adhesive layer 30 are produced, an adhesive foil layer from which the adhesive foil 18 and the adhesive foil layer 32 are produced, and further a bur tape layer from which the bur tape 20 and the bur tape layer 34 are produced. The layers 32, 34, and 36 are preferably separated from the hydrocolloid adhesive body 12, the adhesive foil 18 and the bur tape 20 in the very same process of cutting the adhesive strip assembly from the above described sandwich of layers or alternatively in a separate process.

The rim segments 22 and 24 of the bur tape 20 may be prefabricated prior to the process of cutting the adhesive strip assembly 10 from the above described sandwich as the bur tape 20 may be produced in a configuration in which only the central part of the bur tape is provided with bur loops and in which the rim segments 22 and 24 are not provided with any bur loops. Alternatively, the rim segments 22 and 24 may be produced after the assembly, comprising the siliconized release paper 26, the hydrocolloid adhesive body 12, the adhesive foil 18, and the bur tape 20 has been produced as is disclosed in Fig. 2, by means of heating dies 50 and 52 which are brought into contact with the rim segments of the adhesive strip assembly 10 for removing the bur loops of the bur tape 20 at the rim segments 22 and 24 thereof by melting the bur loops. In Fig. 2, the bur tape 20 is shown in greater details, comprising a support foil 42 from which the loops of the bur tape 20 extend. The reference numerals 44 and 46 define loops of the bur tape 20 provided at the thicker part of the hydrocolloid body 12 and at the rim segment 14 thereof, respectively. After the heating dies 50 and 52 have been removed from contact with the bur tape 20 at the rim segments 22 and 24 thereof, the loops of the bur tape 20 originally present at the rim segment 24 are removed, as is evident from Fig. 3.

In Fig. 4, the adhesive strip assembly 10 is shown in its inten-

tional application for fixating a breast prosthesis, designated the reference numeral 60 in its entirety, to a skin surface part of a woman's thorax. The breast prosthesis 60 is provided with a bur tape component comprising bur hooks 62 adapted to cooperate with the bur loops 44 of the central part of the bur tape 20 of the adhesive strip assembly 10. The hydrocolloid adhesive body 12 is, as is evident from Fig. 4, fixated to a skin surface part 64 and the bur hooks 62 of the breast prosthesis 60 are fixated to the bur loops 44. As the weight of the breast prosthesis 60 generates a force which is transferred to the hydrocolloid adhesive body 12, the force generates a deformation of the subcutaneous area 66 under the skin surface part 64 as the hydrocolloid adhesive body 12 is maintained in facial and adhesive contact with the skin surface part 64 due to the rim segment 14 of the hydrocolloid adhesive body 12 which rim segment circumferentially encloses the entire site of application and fixation of the breast prosthesis 60 relative to the skin surface part.

In Fig. 5, the application of a conventional adhesive strip assembly 10' is shown which is identical to the adhesive strip assembly 10 described above with reference to Figs. 1 and 4, except that the conventional adhesive strip assembly 10' is provided with the bur loops 46 of the bur tape 20 at the rim segment 14 of the hydrocolloid assembly body 12. Fig. 5 illustrates a peeling-off effect originating as the weight of the breast prosthesis 60 is transmitted to the hydrocolloid adhesive body 12 of the assembly 10' and causes a peeling off of the hydrocolloid adhesive body 12 from the skin surface part 64 along the outer rim of the hydrocolloid adhesive body 12. The peeling-off effect is, as is disclosed in Fig. 5, to some extent pronounced in case the bur tape component of the breast prosthesis 60 is not correctly aligned relative to the bur fixation component of the adhesive strip assembly 10', as the incorrect fixation of the breast prosthesis 60 relative to the adhesive strip assembly 10 may give origin to a certain force concentration at the outer rim of the adhesive strip assembly 10, accelerating the peeling-off of the adhesive strip assembly 10' from the skin surface part 64. However, irrespective of the correct or incorrect positioning of the breast prosthesis 60 relative to the conventional adhesive strip assembly 10', the conventional adhesive strip assembly 10' is exposed to the above described peeling-off effect.

The schematic and sectional views of Figs. 4 and 5 are vertical

sectional views illustrating the upper rim of the hydrocolloid adhesive body 12. A similar peeling-off effect may occur at the inner rim segment 14 of the hydrocolloid adhesive body 12 of the adhesive strip assembly 10' shown in Fig. 5. The provision of the rim segments 22 and 24 of the bur tape 20, which rim segments are not adhered or fixated to the breast prosthesis 60, eliminates to any substantial extent the possibility that the adhesive strip assembly 10 for fixating the breast prosthesis 60 is peeled off along the outer rim of the adhesive strip assembly 10 as the rim segments 14 and 16 of the hydrocolloid adhesive body 12 are exposed to forces originating from the weight of the breast prosthesis, generating a force impact substantially along the surface of the skin surface part 64 to which the rim segments 14 and 16 adhere, rather than perpendicularly to the skin surface part 64. The elimination of the peeling-off effect by the provision of the rim segments 14 and 16 of the hydrocolloid adhesive body 12 of the adhesive strip assembly 10 is independent of the positioning of the breast prosthesis 60 relative to the adhesive strip assembly 10, as the elimination of the peeling-off effect by the provision of the adhesive strip assembly 10 is independent of the proper or improper positioning of the breast prosthesis 60 relative to the adhesive strip assembly 10 and, more precisely, independent of whether or not the bur hooks 62 of the breast prosthesis 60 are overlapping the bur loops 44 of the adhesive strip assembly 10 as disclosed in Fig. 5, or correctly aligned relative to the bur loops 44 as disclosed in Fig. 4.

In Fig. 6, an adhesive patch assembly designated the reference numeral 80 in its entirety is shown. The adhesive patch assembly 80 is of an overall configuration corresponding to a surface of contact of a breast prosthesis and basically serves the very same purpose as the adhesive strip assembly 10 described above with reference to Figs. 1 and 4. The adhesive patch assembly 80 comprises a hydrocolloid adhesive body 82 provided with a shallow outer rim segment 84 extending along an outer rim 83 of the adhesive patch assembly 80 and enclosing a central, thicker part of the hydrocolloid adhesive body 82. On top of the hydrocolloid adhesive body 82, an adhesive foil 88 is arranged which adhesive foil is provided with an adhesive layer for the fixation of a bur tape 90. Basically, the hydrocolloid adhesive body 82, the adhesive foil 88, and the bur tape 90 correspond to and serve the same purposes as the hydrocolloid adhesive body 12, the adhesive foil 18, and the bur tape, re-

spectively, of the adhesive strip assembly 10 described above. Like the bur tape 20 described above, the bur tape 90 is provided with bur loops, one of which is designated the reference numeral 94, and which are provided at the central area of the bur tape 90, as the bur tape 90 is not provided with bur loops at the outer rim segment 92 of the bur tape 90 corresponding to the outer rim segment 84 of the hydrocolloid adhesive body 82.

The hydrocolloid body 82 is opposite to the adhesive foil 88 provided with a siliconized release paper 86 serving the same purpose as the siliconized release paper 26 of the adhesive strip assembly 10 described above. The adhesive patch assembly 80 is, like the adhesive strip assembly 10 described above, made from a sandwich of layers from which the siliconized release paper 86, the hydrocolloid adhesive body 82, the adhesive foil 88, and the bur tape 90 are produced, and the adhesive patch assembly 90 further comprises the gripping flap 28 together with the hydrocolloid adhesive layer 32, the adhesive foil layer 34, and the bur tape layer 36 described above with reference to Fig. 10. The circumferential rim segment 92 of the bur tape 90, which circumferential rim segment is not provided with bur loops, may be produced in accordance with the technique described above with reference to Figs. 2 or 3 or, alternatively, the bur tape 90 may be prefabricated prior to the process of cutting the adhesive patch assembly 90 from the above described sandwich in a configuration in which only the central part of the bur tape 90 is provided with bur loops and in which the outer rim segment 92 is not provided with any bur loops.

In Fig. 7, the breast prosthesis 60 is shown in greater details. The prosthesis 60 is provided with bur tape fixation strip segments 68a, 68b, 68c, 68d, and 68e, provided with the bur hooks 62, which strip segments together define a configuration similar to the configuration of the adhesive strip assembly 10. Within the bur tape segments 68a, 68b, 68c, 68d, and 68e, an additional bur fixation 70 is provided, serving the purpose of fixating a perspiration pad 72 to the surface of the breast prosthesis 60 which surface is arranged adjacent to the skin surface part of the woman's thorax. The breast prosthesis 60 is made from a silicone-containing PU foil which is impermeable to humidity. Consequently, unless the perspiration-absorbing pad 72 is provided, the PU foil of the breast prosthesis 60 may cause increased perspiration which apart from discomfort to the woman in question may cause a

reduction of the adhesion of the adhesive strip assembly by means of which the breast prosthesis 60 is fixated to the woman's skin surface part.

Although the present invention has been described above with reference to a specific preferred embodiment of the adhesive strip assembly and further the breast prosthesis, numerous modifications and amendments are readily perceivable to a person having ordinary skill in the art within the protective scope as defined in the appending claims. Thus, although the fixation of the breast prosthesis has been described comprising bur tape fixation, alternative releasable fixations, such as releasable adhesive fixation may be applied. Thus, the breast prosthesis may e.g. be fixated by means of an adhesive foil which is initially fixated to the adhesive strip assembly which is fixated to the woman's skin surface part, and which adhesive foil is provided with non-adhering rim segments similar to the rim segments 22 and 24 of the bur tape 20 described above.

Example

A prototype implementation of the adhesive strip assembly described above with reference to Fig. 10 was made from the following components: The adhesive strip assembly 10 was made from a hydrocolloid adhesive body 12 composed of four adhesive strip segments 11a, 11b, 11c, and 11d, the larger adhesive strip segments 11a and 11b being of identical size, measuring overall length, identical to the maximum dimension of the adhesive strip assembly 10, 137 mm, and width 30 mm, the minor adhesive strip assemblies 11c and 11d being of identical size, measuring overall length 60 mm and width 35 mm. The integral hydrocolloid body 12 composed of the adhesive strip segments 11a-11d was of a maximum thickness at the centre of the hydrocolloid body of the order of 1 mm and a thickness at the inner and outer rim segments 14 and 16 of a thickness of 0.5 mm, the rim segments 14 and 16 being of a width of the order of 5 mm. The bur tape 20 was constituted by a velour bur tape adhered to the hydrocolloid body 12 by means of an acrylic adhesive constituting the adhesive foil 18. The release paper 26 was constituted by a siliconized release paper sheet.

CLAIMS

1. An adhesive strip assembly for fixating a breast prosthesis to a thoracic skin surface, comprising:

- 5 an adhesive strip of a substantially curved configuration corresponding to a part of a circumferential surface of contact of said breast prosthesis at said thoracic skin surface, said adhesive strip defining an outer rim and opposite first and second surfaces, said first surface being provided with an adhesive layer and being adapted to be
10 arranged in contact with said thoracic skin surface for adhering thereto, and

fixation means for releasably fixating said breast prosthesis to said adhesive strip so as to fixate said breast prosthesis to said thoracic skin surface, said fixation means being arranged at said second
15 surface of said adhesive strip covering a part of said second surface thereof and providing an uncovered circumferential surface segment of said second surface adjacent to said outer rim of said adhesive strip.

2. The adhesive strip assembly according to Claim 1, said fixation means being fixated to said adhesive strip at said second surface thereof through an adhesive foil.
20

3. The adhesive strip assembly according to any of the Claims 1-2, further comprising a release paper sheet covering said first surface of said adhesive strip prior to the use of said adhesive strip assembly.

4. The adhesive strip assembly according to any of the claims 1-3, said fixation means being constituted by an adhesive layer provided at
25 said second surface of said adhesive strip.

5. The adhesive strip assembly according to any of the claims 1-3, said fixation means being constituted by bur fixation means adapted to cooperate with mating bur fixation means provided at said circumferential surface of contact of said breast prosthesis.
30

6. The adhesive strip assembly according to Claim 5, said bur fixation means being provided by a bur tape applied to said second side of said adhesive strip.

7. The adhesive strip assembly according to any of the Claims 5 or
35 6, said bur fixation means comprising bur loops.

8. The adhesive strip assembly according to any of the Claims 5 or 6, said bur fixation means comprising bur hooks.

9. The adhesive strip assembly according to any of the Claims 6-8, said uncovered surface segment of said second surface of said adhesive strip being constituted by a surface segment of said bur tape not being provided with bur fixation means.

10. The adhesive strip assembly according to any of the Claims 1-9, said adhesive strip comprising a hydrocolloid adhesive layer.

11. An adhesive patch assembly for fixating a breast prosthesis to a thoracic skin surface, comprising:

an adhesive patch of a configuration corresponding to a part of a surface of contact of said breast prosthesis at said thoracic skin surface, said adhesive patch defining an outer rim and opposite first and second surfaces, said first surface being provided with an adhesive layer and being adapted to be arranged in contact with said thoracic skin surface for adhering thereto, and

fixation means for releasably fixating said breast prosthesis to said adhesive patch so as to fixate said breast prosthesis to said thoracic skin surface, said fixation means being arranged at said second surface of said adhesive patch covering a part of said second surface thereof and providing an uncovered circumferential surface segment of said second surface adjacent to said outer rim of said adhesive patch.

12. The adhesive patch assembly according to Claim 11, said fixation means being fixated to said adhesive patch at said second surface thereof through an adhesive foil.

13. The adhesive patch assembly according to any of the Claims 11-12, further comprising a release paper sheet covering said first surface of said adhesive patch prior to the use of said adhesive patch assembly.

14. The adhesive patch assembly according to any of the claims 11-13, said fixation means being constituted by an adhesive layer provided at said second surface of said adhesive patch.

15. The adhesive patch assembly according to any of the claims 11-13, said fixation means being constituted by bur fixation means adapted to cooperate with mating bur fixation means provided at said circumferential surface of contact of said breast prosthesis.

16. The adhesive patch assembly according to Claim 15, said bur fixation means being provided by a bur tape applied to said second side of said adhesive patch.

17. The adhesive patch assembly according to any of the Claims 15 or 16, said bur fixation means comprising bur loops.

18. The adhesive patch assembly according to any of the Claims 15 or 16, said bur fixation means comprising bur hooks.

5 19. The adhesive patch assembly according to any of the Claims 16-18, said uncovered surface segment of said second surface of said adhesive patch being constituted by a surface segment of said bur tape not being provided with bur fixation means.

10 20. The adhesive patch assembly according to any of the Claims 11-19, said adhesive patch comprising a hydrocolloid adhesive layer.

21. A breast prosthesis assembly comprising a breast prosthesis and an adhesive strip assembly for fixating said breast prosthesis to a thoracic skin surface,

said breast prosthesis comprising:

15 a breast prosthesis body of a configuration similar to a woman's natural breast and defining a surface of contact to be arranged adjacent to said thoracic skin surface,

said adhesive strip assembly comprising:

20 an adhesive strip of a substantially curved configuration corresponding to a part of a circumferential part of said surface of contact of said breast prosthesis body, said adhesive strip defining an outer rim and opposite first and second surfaces, said first surface being provided with an adhesive layer and being adapted to be arranged in contact with said thoracic skin surface for adhering thereto, and

25 fixation means for releasably fixating said breast prosthesis to said adhesive strip so as to fixate said breast prosthesis to said thoracic skin surface, said fixation means being arranged at said second surface of said adhesive strip covering a part of said second surface thereof and providing an uncovered circumferential surface segment of
30 said second surface adjacent to said outer rim of said adhesive strip.

22. The breast prosthesis assembly according to Claim 21, said adhesive strip assembly comprising any of the characteristics of the Claims 2-10.

35 23. The breast prosthesis assembly according to any of the Claims 21-22, said breast prosthesis body comprising a bur fixation means provided at said surface of said breast prosthesis body for fixating a perspiration pad to said surface.

24. The breast prosthesis assembly according to any of the Claims 21-23, said breast prosthesis body comprising an outer PU foil enclosing a silicone filling thereof.

25. A breast prosthesis assembly comprising a breast prosthesis and
5 an adhesive patch assembly for fixating said breast prosthesis to a thoracic skin surface,

said breast prosthesis comprising:

a breast prosthesis body of a configuration similar to a woman's natural breast and defining a surface of contact to be arranged adjacent
10 to said thoracic skin surface,

said adhesive patch assembly comprising:

an adhesive patch of a configuration corresponding to a part of said surface of contact of said breast prosthesis body, said adhesive patch defining an outer rim and opposite first and second surfaces, said
15 first surface being provided with an adhesive layer and being adapted to be arranged in contact with said thoracic skin surface for adhering thereto, and

fixation means for releasably fixating said breast prosthesis to said adhesive patch so as to fixate said breast prosthesis to said thoracic skin surface, said fixation means being arranged at said second
20 surface of said adhesive patch covering a part of said second surface thereof and providing an uncovered surface segment of said second surface adjacent to said outer rim of said adhesive patch.

26. The breast prosthesis assembly according to Claim 25, said adhesive patch assembly comprising any of the characteristics of the
25 Claims 12-20.

27. The breast prosthesis assembly according to any of the Claims 25-26, said breast prosthesis body comprising a bur fixation means provided at said surface of said breast prosthesis body for fixating a per-
30 spiration pad to said surface.

28. The breast prosthesis assembly according to any of the Claims 26-27, said breast prosthesis body comprising an outer PU foil enclosing a silicone filling thereof.

29. A breast prosthesis comprising:

a breast prosthesis body of a configuration similar to a woman's natural breast and defining a surface of contact to be arranged adjacent to said thoracic skin surface, and a bur fixation means provided at said
5 surface of said breast prosthesis body for fixating a perspiration pad to said surface.

30. The breast prosthesis assembly according to Claim 29, said breast prosthesis body comprising an outer PU foil enclosing a silicone filling thereof.

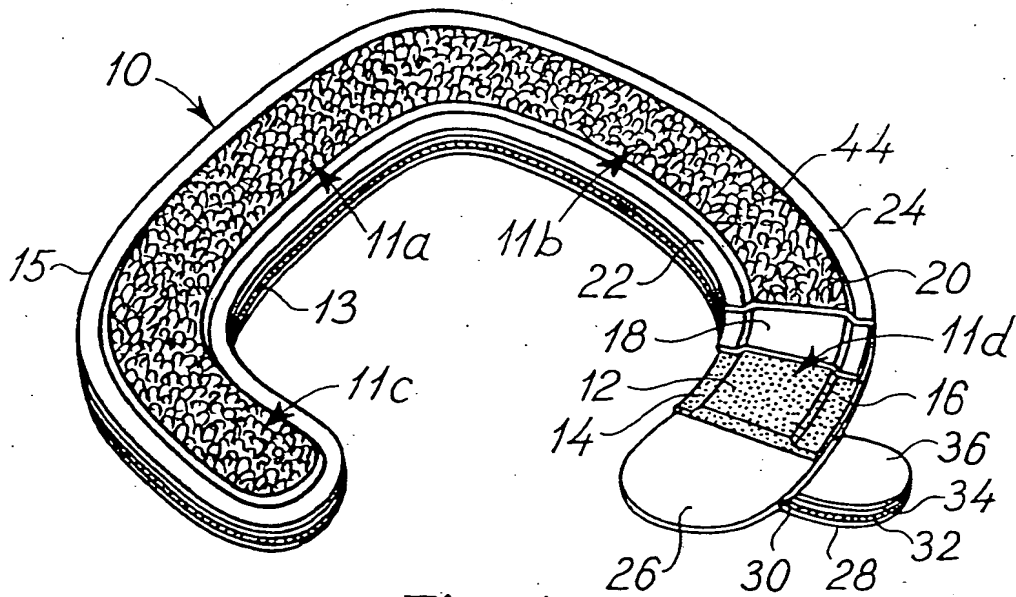


Fig. 1

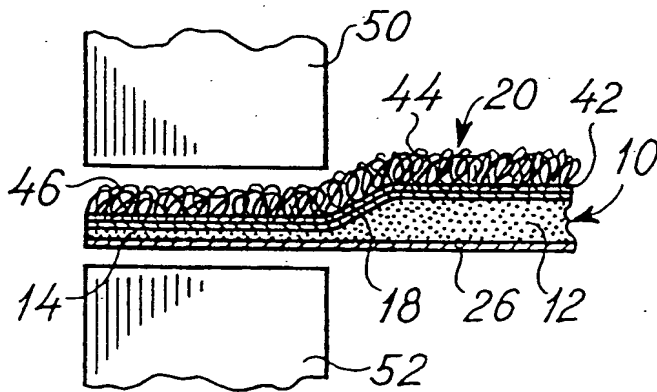


Fig. 2

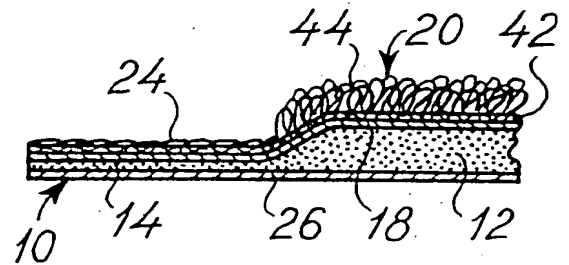


Fig. 3

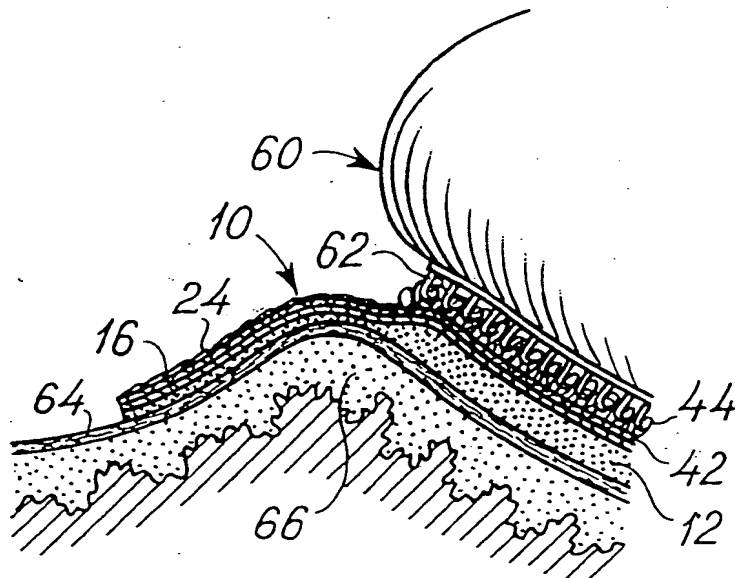


Fig. 4

2 / 2

Fig. 6

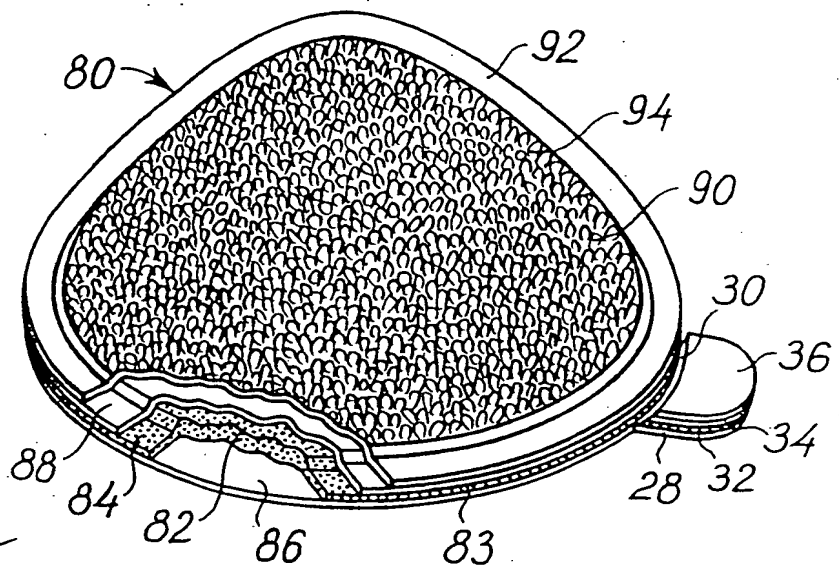


Fig. 5

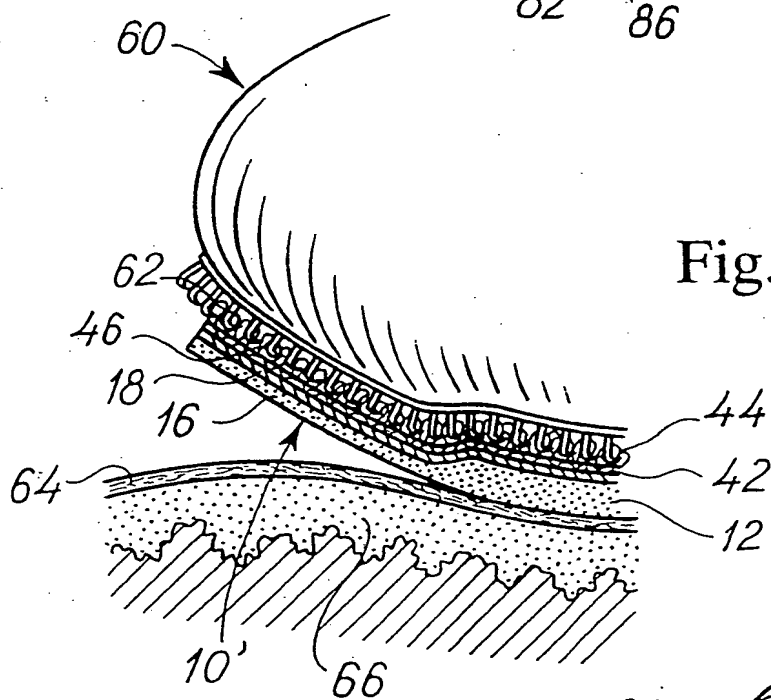
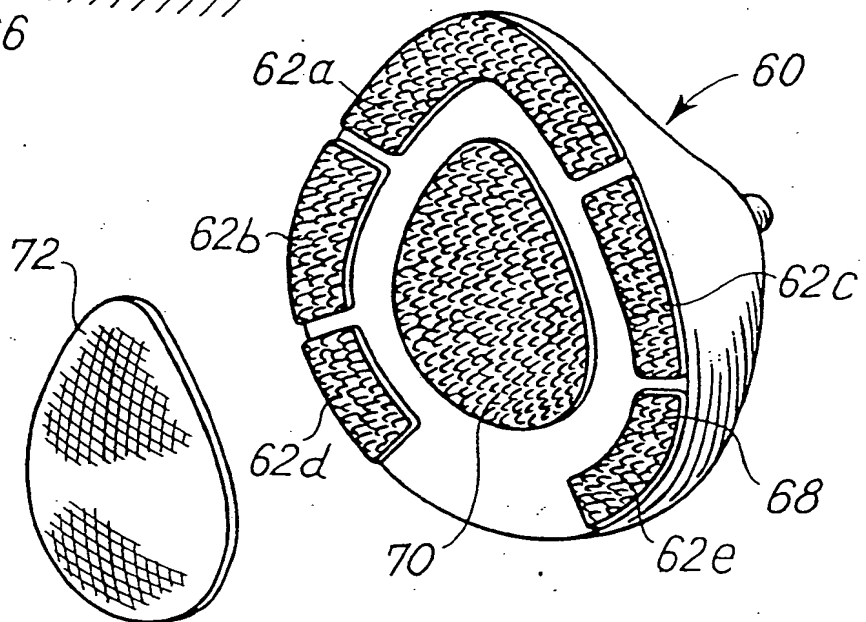


Fig. 7



INTERNATIONAL SEARCH REPORT

International application No.

PCT/DK 94/00047

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61F 2/52

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP, A1, 0392960 (COLOPLAST A/S), 17 October 1990 (17.10.90), column 4, line 5 - column 7, line 22; column 8, line 4 - line 11	1-20
Y	---	21-30
Y	DE, A1, 2742394 (LOHSE, MARIA), 29 March 1979 (29.03.79), page 6, line 21 - page 7, line 4, figures 1-5	1-4, 11-14
X	GB, A, 2202745 (CRAIG MEDICAL PRODUCTS LIMITED), 5 October 1988 (05.10.88), figure 5, claims 1-6	1-4, 9
Y	---	11-14, 19, 21-30

☒ Further documents are listed in the continuation of Box C.☒ See patent family annex.

* Special categories of cited documents:

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

27 April 1994

Date of mailing of the international search report

29 -04- 1994

Name and mailing address of the ISA/
Swedish Patent Office
Box 5055, S-102 42 STOCKHOLM
Facsimile No. +46 8 666 02 86

Authorized officer

Christian Westberg
Telephone No. +46 8 782 25 00

INTERNATIONAL SEARCH REPORT

International application No.

PCT/DK 94/00047

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	DE, A1, 2802375 (KNOCHE, BODO), 26 July 1979 (26.07.79), page 8, figures 1-3 -----	28,30

INTERNATIONAL SEARCH REPORT

Information on patent family members

26/02/94

International application No.

PCT/DK 94/00047

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP-A1- 0392960	17/10/90	SE-T3- 0392960 DE-T- 69002671 JP-A- 2291856 US-A- 5071433	25/11/93 03/12/90 10/12/91
DE-A1- 2742394	29/03/79	NONE	
GB-A- 2202745	05/10/88	NONE	
DE-A1- 2802375	26/07/79	NONE	